# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. PEGGY RYAN.

Plaintiffs,

Case No. 05-cv-3450

v.

ENDO PHARMACEUTICALS, INC.,

Defendant.

#### MOTION FOR RELATOR'S SHARE AWARD

#### I. Introduction

In July 2005, Relator Peggy Ryan filed a False Claims Act complaint in the Eastern District of Pennsylvania alleging a massive, fraudulent, off-label marketing and promotional scheme of Endo Pharmaceutical's flagship drug, Lidoderm. The decision to file a False Claims Act case is an extremely difficult one for any relator, but particularly for a young professional nearing the height of her career who is risking everything in the name of doing what is right for taxpayers and the United States. At that time, Ryan could not have known of the arduous process she would face as a result of filing her case – nearly a decade of living a double life while she secretly assisted the United States' investigation, wearing a wire to record hundreds of hours of conversations exposing Endo's intent to market Lidoderm off-label, poring over thousands of pages of documents to identify evidence of Endo's knowingly fraudulent conduct, meeting after meeting to push the case forward in the face of constant prosecutor and agent turnover, and a health crisis brought to the surface as a result of the relentless pressure of being a relator. But even had she known what was to come, Ryan's personal commitment to honesty left

her with no choice: she had to take the daunting step of becoming the only person out nearly a thousand sales representatives at Endo Pharmaceuticals to stand up and demand that the company be held accountable for its blatant fraud.

In February 2014 Ryan was vindicated. The United States of America and forty-seven states reached a settlement agreement with Endo Pharmaceuticals whereby Endo agreed to pay \$192.7 million to resolve criminal and civil off-label marketing allegations. From that settlement, \$137.7 million was allocated to the federal Government's civil False Claims Act claims. In addition to the financial settlement, Ryan and the Government stopped Endo's conduct from continuing to harm the U.S. taxpayers and users of the Lidoderm patch. The False Claims Act provides that, in a successful case where the Government intervenes and obtains a recovery from a Relator's case, the Relator shall be entitled to 15% to 25% of the proceeds, "depending on the extent to which the person substantially contributed to the prosecution of the action." 31 U.S.C. § 3730(d)(1).

As detailed more fully herein, Ryan "substantially contributed" to the Government's case in the exact manner which Congress anticipated when it created the relator's share award provision. Throughout the entire nine-year investigation, Ryan has been the Government's staunchest ally in pushing this case to a resolution. It is not an overstatement to say that, without Ryan's commitment to gathering evidence and supporting the Government's investigation, the ultimate resolution would not have been attained.

However, although Ryan and the Government have worked side-by-side for nearly a decade, they have been unable to reach an agreement as to the appropriate percentage of the

federal civil settlement that fairly and justly rewards Ryan's contributions to the case. A relator's share dispute is an unenviable position for any relator, but particularly for Ryan, who finds herself in an adversarial position against the Government after having stood as its ally for so many years. *U.S ex rel. Alderson v. Quorum Health Group, Inc.*, 171 F.Supp.2d 1323, 1340 (M.D. Fla. Nov. 8, 2001)(recognizing the "troubling" adversarial position in which the U.S. and relator find themselves "even after years of splendid and sometimes inspired endeavor").

Although Ryan and the Government are in opposition with one another at this juncture, the Government uniquely possesses much of the information that supports Ryan's case. *U.S. v. U.S. ex rel. Thornton*, 207 F.3d 769, 773 (5th Cir.2000)("The government has not always been magnanimous to its relators at the end of the day. They cannot easily part ways at this stage, however: the relator must rely to some extent on the government to report in good faith the fruits of their joint efforts."). Therefore, in support of this motion for a relator's share award, Ryan relies on the Government to accurately represent the nature of her contributions to their nine-year investigation, as well as her on own declaration ("Ryan Declaration," attached here to as Exhibit A), the declaration of her counsel's lead investigator Al Scudieri ("Scudieri Declaration," attached hereto as Exhibit B), and the declaration of Chris Mulhall, the former FBI agent who originated and oversaw the investigation into Endo Pharmaceuticals ("Mulhall Declaration," attached hereto as Exhibit C).

For the following reasons, Ryan hereby moves this honorable Court for a determination that she is entitled to a 24% relator's share award in recognition of her contributions to the government's \$137.7 million federal civil recovery from Endo Pharmaceuticals.

<sup>&</sup>lt;sup>1</sup> Ryan's counsel began negotiating with the Government to reach an agreement on this issue shortly after the Court's June 23<sup>rd</sup> Order, but the parties are at an impasse.

# II. Procedural History

The Court being well-versed in the procedural history of this case, the following recitation addresses only the aspects immediately relevant to this motion. *See* Dkt. 41 at 2-7. Relator Peggy Ryan first filed a False Claims Act case against Endo Pharmaceuticals on July 5, 2005. Dkt. 1. As a direct result of Ryan's complaint, the Government initiated a multi-agency investigation into Endo's off-label marketing of its flagship drug, Lidoderm. At the Government's request, Ryan agreed to allow the case to be placed in civil suspense in September 2006 while she continued to work with the Government to develop the investigation. Dkt. 6. In January 2007, the FBI and HHS-OIG served a subpoena on Endo seeking documents in support of Ryan's allegations of off-label marketing. Ryan entered into an "Agreement Regarding Common Interest and Disclosure of Information" in March 2008, enabling her to review the documents produced by Endo in response to the subpoena.

Ryan stayed in her position at Endo from the time she filed her case until her early resignation in 2012 for health reasons. As a result of her on-going employment, Ryan continued to develop information that supported and expanded the details of her off-label allegations. Thus, as a result of the information developed in the course of her employment, Ryan filed amended complaints in April 2009 ("First Amended Complaint"), September 2010 ("Second Amended Complaint"), and January 2011 ("Third Amended Complaint"). Dkts. 7, 8, and 12, respectively.

On February 21, 2014, nearly nine years after Ryan's initial complaint, the United States, forty-seven states, and the District of Columbia announced a settlement agreement with Endo Pharmaceuticals, whereby Endo agreed to pay \$171,910,153 plus accrued interest to resolve the state and federal civil allegations of off-label marketing. The resolution also included a \$20.8

million criminal restitution and a deferred prosecution agreement related to one charge of criminal misbranding. In addition, Endo agreed to put in place several enhanced compliance programs and to abide by the terms of a five-year Corporate Integrity Agreement. Ryan's case, and the cases of two late-filed relators, Max Weathersby and Gursheel Dhillon, were resolved in the settlement, but the issue of relator's share was specifically reserved.

Following the settlement, Ryan and the two late-filed relators litigated the issue of entitlement to a relator's share award. On June 23, 2014, this Court issued an order determining, *inter alia*, that, "Weathersby and Dhillon are prohibited from asserting such claims by the bar of the first-to-file rule, 31 U.S.C. § 3730(b)(5). Consequently, we find that Ryan is the sole Relator eligible for the settlement award." Dkt. 41 at 16. In reaching its decision, the Court also noted that, "[A]s a practical matter, we believe this result is justified by the extensive role Ryan played in procuring the settlement with the Defendants." *Id.* at 26. "Ryan supplied the Government with the initial notification of Defendants' fraudulent activities and then proceeded to go to extraordinary lengths to provide further information to aid the Government in prosecuting the FCA action." *Id*.

Third-filed relator Gursheel Dhillon has appealed this Court's decision, seemingly arguing that the Court erred in finding Ryan to be the sole relator entitled to a relator's share award, but failing to articulate any coherent or legally-supported basis for his appeal. Dhillon has failed to post the \$10,000 appellate bond that this Court has required of him, and Ryan has filed the appropriate motion with the Third Circuit to dismiss Dhillon's appeal for failure to post the bond. *Dhillon v. Ryan*, Case No. 14-3377 (3d Cir.2014), at Dkt. 003111774578. Ryan has also filed a motion to summarily affirm this Court's order, based on the clear frivolousness of Dhillon's appeal. *Id.* at Dkt. 003111763918.

Neither Dhillon nor the Government has moved to stay the Court's June 23<sup>rd</sup> Order, nor would a stay be appropriate given the abject lack of legal basis for Dhillon's appeal. *Howes v. Med. Components, Inc.*, 741 F.Supp. 528, 531 (E.D.P.A. June 1, 1990)(in weighing a request to stay an injunction pending an appeal, courts are to "(1) assess the movant's chances for success on appeal and (2) weight the equities as they affect the parties and the public at large."). Additionally, the Government has informed Ryan that the money set aside to pay the relator's share award is currently held in a non-interest-bearing account, which means that Ryan is being financially harmed every day that her relator's share payment is delayed. Therefore, it is the most efficient use of time to proceed with the relator's share briefings during the pendency of Dhillon's frivolous appeal in order to minimize the delay in the resolution of this issue and the corresponding financial harm to Ryan.

### A. State Relator's Share Award

Although the Endo Settlement Agreement included both federal and state shares, only the federal share is at issue in this motion. Following this Court's June 23<sup>rd</sup> Order, Relator Peggy Ryan reached an agreement with the Medicaid Participating States whereby the states awarded Ryan a 22% relator's share award from the amount of the settlement allocated to New York and Florida. Ryan executed a relator's share agreement with the states on August 4, 2014, and the states have paid Ryan \$3,765,244.96 representing her 22% share of the proceeds, plus post-settlement interest.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> The state relator's share is derived from a separate pool of money than the federal relator's share, so it is not an off-set of the amount owed in relation to the federal relator's share.

### III. Applicable Law

#### A. Entitlement to Relator's Share Award

The False Claims Act sets a range of awards for a relator in a successful case depending on the role the Government assumed in the case. If the Government intervenes, the relator is entitled to a 15% to 25% share of the proceeds of the case. 31 U.S.C. § 3730(d)(1). The statute does not differentiate between a case where the Government intervened shortly after filing or where, as in the instant case, the Government refrained from making an intervention decision for many years and ultimately intervened only for purposes of settlement. The False Claims Act also provides for scenarios which do not apply to the instant case, such as a higher percentage bracket for non-intervened cases, or reductions if a case is based on public disclosures or brought by a person who initiated the fraud scheme. 31 U.S.C. § 3730(d).

The False Claims Act does not expressly provide enumerated factors to be considered in determining the amount of a relator's share award. 31 U.S.C. § 3730(d)(1). However, certain maxims have been developed through case law which reflect that the baseline 15% is viewed strictly as a "finder's fee" for a person who does little more than simply file the case, while the maximum is appropriate for cases in which a relator actively and uniquely aids the government in the prosecution of the case. *Alderson*, 171 F.Supp.2d at 1331 ("The fifteen percent minimum share is generally viewed as a finder's fee"); *U.S. ex rel. Burr v. Blue Cross and Blue Shield of Florida*, 883 F.Supp. 166, 168(M.D. Fla. Mar. 23, 1995)("[T]he maximum recovery is reserved for situations where the relator actively and uniquely aids the government in the prosecution of the case."). Further, "the lower end of the range is generally appropriate for Relators who have failed to substantially contribute to successful resolution of the case or have hindered its investigation." *U.S. ex rel. Rille v. Hewlett Packard Co.*, 784 F.Supp.2d 1097, 1101 (E.D. Ark.

Mar. 18, 2011). Finally, courts have agreed that when the Government and a relator cannot reach an agreement as to the percentage of the relator's share award, the percentage to be awarded is within the district court's discretion. *U.S. ex rel. Johnson-Pochardt v. Rapid City Reg'l Hosp.*, 252 F.Supp.2d 892, 897 (D.S.D. Feb. 26, 2003), citing *Alderson*, 171 F.Supp.2d at 1331.

#### **B.** Factors Used to Determine Relator's Share

The False Claims Act does not provide any factors to determine where a relator's share should fall in the prescribed range, beyond considering "the extent to which the [relator] substantially contributed to the prosecution of the action." 31 U.S.C. § 3730(d)(1). However, the Senate Report from the 1986 amendments that created the modern False Claims Act provided three factors to be considered: (1) the significance of the information provided to the government; (2) the contribution of the person bringing the action to the result obtained; and (3) whether the information that formed the basis for the suit was known to the Government.

\*\*Alderson\*, 171 F.Supp.2d at 1332, citing S.Rep. No. 99–345, at 28 (1986).

The legislative history of the House of Representatives' version of the 1986 amendments also described the appropriate considerations in determining a relator's share award:

If the Government comes into the case, the person is guaranteed a minimum of 15% of the total recovery even if that person does nothing more than file the action in federal court. This is in the nature of a "finder's fee" and is provided to develop incentives for people to bring the information forward. The person need do no more than this to secure an entitlement to a minimum 15%. In those cases where the person carefully develops all the facts and supporting documentation necessary to make the case and presents it in a thorough and detailed fashion to the Justice Department as required by law, and where that person continues to play an active and constructive role in the litigation that leads ultimately to a successful recovery to the United States Treasury, the Court should award a percentage substantially above 15% and up to 25%.

132 Cong. Rec. H9382-83 (Oct. 7, 1986)(statement of Rep. Howard Berman).

In 1996, the U.S. Department of Justice ("DOJ") adopted a set of internal guidelines to assist DOJ attorneys in negotiating relator's share awards or proposing an amount to a court. *Alderson*, 171 F.Supp.2d at 1333. DOJ's "Relator's Share Guidelines" recommend that the Government start its relator's share determination at the 15% base and then provides a series of factors which the Government believes could increase the relator's share award, <sup>3</sup> and a series of factors which the Government believes could decrease the relator's share award. <sup>4</sup> The Guidelines are silent on whether each factor is equal to every other factor, or how much weight any particular factor should be given.

The Department of Justice's internal guidelines have been criticized for being "noticeably unhelpful" and inconsistent. *See, e.g., Alderson*, 171 F.Supp.2d at 1334 ("[T]he DOJ guidelines

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<sup>&</sup>lt;sup>3</sup> "Items for Consideration for a Possible Increase in the Percentage" include "(1) the relator reported the fraud promptly; (2) when he learned of the fraud, the relator tried to stop the fraud or reported it to a supervisor or the Government; (3) the *qui tam* filing, or the ensuing investigation, caused the offender to halt the fraudulent practices; (4) the complaint warned the Government of a significant safety issue; (5) the complaint exposed a nationwide practice; (6) the relator provided extensive, first-hand details of the fraud to the Government; (7) the Government had no knowledge of the fraud; (8) the relator provided substantial assistance during the investigation and/or pretrial phases of the case; (9) at his deposition and/or trial, the relator was an excellent, credible witness; (10) the relator's counsel provided substantial assistance to the Government; (11) the relator and his counsel supported and cooperated with the Government during the entire proceeding; (12) the case went to trial; (13) the FCA recovery was relatively small; (14) the filing of the complaint had a substantial adverse impact on the relator."

<sup>&</sup>lt;sup>4</sup> "Items for Consideration for a Possible Decrease in the Percentage" include "(1) the relator participated in the fraud; (2) the relator substantially delayed in reporting the fraud or filing the complaint; (3) the relator, or relator's counsel, violated FCA procedures: complaint served on defendant or not filed under seal; the relator publicized the case while it was under seal; statement of material facts and evidence not provided; (4) the relator had little knowledge of the fraud or only suspicions; (5) the relator's knowledge was based primarily on public information; (6) the relator learned of the fraud in the course of his Government employment; (7) the Government already knew of the fraud; (8) the relator, or relator's counsel, did not provide any help after filing the complaint, hampered the Government's efforts in developing the case; or unreasonably opposed the Government's positions in litigation; (9) the case required substantial effort by the Government to develop the facts to win the lawsuit; (10) the case settled shortly after the complaint was filed or with little need for discovery; (11) the FCA recovery was relatively large."

fail to establish a coherent theory under which to determine the relator's share. Notably, the guidelines, or at least some of their underlying premises, contradict one another."); Johnson-Pochardt, 252 F.Supp.2d at 900. Many of the factors in the DOJ Guidelines have been specifically rejected by courts as well. For example, the Government recommends reducing the relator's share award for a large settlement and increasing it for a relatively small settlement. Not only is it inherently illogical to reward efforts bringing about a small recovery more than those that bring about a large recovery, but such a limiting factor is contrary to Congress' purpose in establishing a relator's share award. Johnson-Pochardt, 252 F.Supp.2d at 903 ("Congress did not establish a sliding scale to graduate the available percentages as the size of the recovery increases.")(internal quotations omitted); U.S. ex rel. Merena v. SmithKline Beecham Corp. ("Merena I"), 52 F.Supp.2d 420 (E.D. Pa. Apr. 8, 1998), rev'd on other grounds, 205 F.Supp.3d 97 (3d Cir.2000)("An Act of Congress provides for substantial awards in order that persons who acquire first-hand knowledge of false claims being presented to the Government will come forth and file meritorious qui tam complaints. The success of this legislation in continuing to achieve its goals can only be assured by unstintingly providing the qui tam awards dictated by Congress, irrespective of the size of the awards."). As a result, "the DOJ guidelines are merely an indiscriminate enumeration of more or less obvious factors, unaccompanied by any indication of comparative weight and more useful as a checklist for negotiation than a rule of decision in an adjudication." Alderson, 171 F.Supp.2d at 1334, n.34.

#### IV. Argument for Federal Relator's Share

There is no consistent or accepted methodology for applying the factors in determining an appropriate relator's share award. While no courts have used DOJ's Guidelines exclusively, some have created a hybrid analysis blending the Senate factors and the DOJ Guidelines, and

others have largely rejected the Guidelines in favor of the Senate factors. *See*, e.g., *Johnson-Pochardt*, 252 F.Supp.2d at 899-904; *Alderson*, 171 F.Supp.2d at 1333-34. Some courts have reached a decision without identifying any methodology at all, while others have foregone any specific methodology in favor of simply making an overall assessment based on the extent to which the relator substantially contributed to the successful resolution of the case. *U.S. ex rel. Pedicone v. Mazak Corp.* 807 F.Supp. 1350, 1353 (S.D. Ohio Oct. 16, 1992); *Merena I*, 52 F.Supp.2d at 449-50.

For purposes of this analysis, Relator Ryan believes that the factors enumerated in the Senate legislative history are the most appropriate because they reflect Congress's intent in creating the relator's share award, which is the metric the Third Circuit has favored in conducting False Claims Act statutory interpretations. *See U.S. ex rel. Merena v. SmithKline Beecham Corp.* ("Merena II"), 205 F.3d 97, 105-06 (3d Cir.2000)(evaluating Congress's intentions to determine the appropriate bracket for a relator's share award with respect to a claim precluded by the public disclosure bar).

As discussed more fully below, it is indisputable that Ryan's contributions to the Government's investigation of Endo Pharmaceuticals were extraordinary and entitle her to the maximum or nearly the maximum allowable percentage of the civil settlement as her relator's share award.

# A. The information that Ryan produced to the Government was significant and unobtainable by any other means.

Before Peggy Ryan formally filed her *qui tam* complaint in the Eastern District of Pennsylvania, Ryan's counsel made a pre-filing disclosure of the off-label allegations to FBI Agent Chris Mulhall, then the supervisor-in-charge of healthcare fraud investigations for the Northern District of New York. Scudieri Declaration at ¶ 5. The information that Al Scudieri,

the chief investigator at the James Hoyer law firm, provided to Mulhall prompted Mulhall to immediately open an investigation and assign FBI agent Mike Hensle to investigate the allegations. Mulhall Declaration at ¶ 2.

Just two days after Ryan's complaint was filed, she attended her first meeting with Agent Hensle and Lisa Girardi of the U.S. Department of Health and Human Services in the FBI's offices in Syracuse, New York. Ryan Declaration at ¶ 16. After Ryan provided her personal background information and general corporate information pertaining to Endo, she provided Hensle and Girardi with documentary evidence she had gathered in support of her allegations. The documents included Endo's promotional sales materials, including off-label studies, the Restricted Materials Logs where sales representatives were required to record the amount of off-label material which had been provided to physicians, and call plans requiring sales representatives to promote Lidoderm to physicians who would not have been treating patients with post-herpetic neuralgia (the only on-label indication of Lidoderm). *Id.* at ¶ 9, 12.

It was at this initial meeting that the Government first proposed the idea of equipping Ryan with a surreptitious recording device to obtain covert recordings of conversations with Endo executives that could reveal knowing and intentional efforts to defraud Medicare and Medicaid through off-label marketing. Ryan Declaration at ¶ 16. Hensle and Girardi asked Ryan if she had any connections that would allow her to get into Endo's corporate headquarters to make recordings. *Id.* Because of the level of esteem with which Ryan was held by Endo executives, she did. Ryan agreed to reach out to Endo's Director of Marketing, Deanne Melloy, with whom she had developed a relationship when Ryan was selected to join corporate executives on a trip to Japan (where Lidoderm is manufactured) as the recipient of Endo's "Japan Rising Sun" award. *Id.* 

Before the meeting with Melloy was scheduled, Ryan received word from Endo that her District Manager, Gail Pierce, would be visiting Upstate New York to conduct a ride-along with Ryan. Ryan Declaration at ¶ 17. Ryan, through her counsel, notified the Government of this meeting, and the FBI quickly moved to have Ryan wired for the duration of the ride-along. *Id.* Equipped with a small transmitting device concealed under her blouse, Ryan recorded eight hours of meetings with Pierce on or about August 1, 2005 – less than one month after filing her complaint. *Id.* Ryan captured Pierce, an Endo manager, directing Ryan on how to use certain phrases to encourage physicians to "put the patch where the pain is" – Endo's slogan which was geared towards promoting Lidoderm for off-label uses. *Id.* 

A month later, in September 2005, the FBI once again sought Ryan's agreement to be wired for a "Plan of Action" meeting led by Endo Regional Business Director and Specialty District Manager J.P. Brassil. Ryan Declaration at ¶ 18. The meeting was attended by the specialty sales force, the pharmaceutical sales force, and members of Endo's management team including Specialty District Manager Anthony Luongo and Pharmaceuticals District Manager Joe Gaeta. *Id.* Over the full-day meeting, Ryan recorded Brassil instructing the sales force on how to position off-label usage of Lidoderm through leading and engaging questions. *Id.* Ryan also questioned Brassil about a comment he made regarding the potential for increased FDA scrutiny. Brassil responded, on the recording, that Endo may get on the FDA's radar because, "the fact that we're a pain management company, the fact this is not a \$40 million product any more. It's a \$400 million product, but 90% of our prescriptions come off-label." *Id.* After the FBI reviewed the transcripts of the August and September recordings, Hensle stated of the Brassil recordings, "This is the jackpot!" *Id.* There is no way the Government would have had access to these recorded meetings if not for Ryan.

Ryan's formal Relator's Meeting occurred on November 3, 2005. By the time of this meeting, the Government had rallied representatives from several different departments to participate in the investigation. Ryan's Relator's Meeting brought together Hensle, Girardi, Ronald Houston of the Food & Drug Administration, AUSA Tom Capezza from the Northern District of New York, AUSA Peg Hutchinson from the Eastern District of Pennsylvania, and Dana Fink from the New York Office of Probation. As with the first meeting with Hensle and Girardi, Ryan proved herself to be a credible witness by providing details on her personal and professional background, as well as extensive insider information and documentation about Endo's corporate culture of off-label marketing. Ryan Declaration at ¶ 20. Following this meeting, Ryan and her counsel came to understand that the Government organized a task force whereby the various departments could all work in tandem to ensure the investigation was conducted efficiently and effectively.

As the investigation progressed, Ryan continued to provide unique and otherwise unobtainable evidence through insider documents and recordings. Ryan Declaration at ¶ 21. As Hensle had requested, Ryan set up a two-day session to shadow Endo's Senior Director of Marketing Deanne Melloy at the company's headquarters in Chadd's Ford, Pennsylvania, on April 20 and 21, 2006. Ryan Declaration at ¶ 22. Ryan obtained permission for the shadowing visit from her immediate director under the auspices of obtaining marketing tips to bring back to the Upstate New York region. During the twenty-plus hours of recordings, Ryan captured Melloy reciting data such as 4% of Lidoderm prescribers were responsible for more than 50% of Lidoderm prescriptions, and that Endo had not yet begun to fully saturate the Medicaid marketplace. Melloy also had Ryan meet with Bill Kellens, Endo's Lidoderm Product Manager, who openly stated that 97-98% of Endo's Lidoderm prescriptions were off-label. *Id.* Melloy

invited Ryan to attend the "Lidoderm 2006 Situational Analysis Meeting" led by Senior Market Research Analyst Alex Arfaei. *Id.* Ryan's recording of this meeting, and the attendant Power Point presentation which she obtained at the meeting, provided critical evidence of Endo's intent to market Lidoderm off-label, as Arfaei confirmed that Lidoderm business was driven by low back and acute pain, and the slides confirmed that Endo viewed Lidoderm to be in competition with drugs which did not treat PHN (the only on-label use) but rather other types of pain.

As the evidence from Ryan's recordings mounted, the Government began to prepare a subpoena to issue to Endo to obtain additional documents and information supporting Ryan's allegations. Relying on Ryan's detailed recollection and insider knowledge, the Government held a meeting on October 17, 2006, with Ryan and her counsel to discuss the pending subpoena and to obtain Ryan's insights on how to sharpen and target the request for information. Ryan Declaration at ¶ 23. Ryan provided specific information to prosecutors and agents from the FBI, HHS-OIG, FDA, and AUSAs from the Northern District of New York regarding categories of documents, who would be in possession of the most significant documents, where the documents would be located, potential witnesses who should be interviewed after the subpoena was served, and targeted questions to be asked of the sales and marketing forces during the interviews. *Id.* at 23, 24; Mulhall Declaration at ¶ 6.

Once the subpoena was prepared, the Government specifically timed the service of the subpoena to coincide with two simultaneous Endo regional sales meetings in Baltimore, Maryland and Los Angeles, California, on January 17, 2007. *Id.* at ¶ 25. While Ryan attended the East coast conference wearing her concealed recording device, her hotel room was filled with FBI and HHS agents preparing to execute the subpoena. When Endo CEO Peter Lankau announced the subpoena to the conference attendees, Ryan was forced to feign ignorance and act

as though she was just as shocked by the announcement as her colleagues. Ryan stood by and watched as the Government selected Endo employees to be interviewed – the same employees that Ryan had identified as key witnesses to the off-label scheme. *Id.* at 25, 26.

The Government has acknowledged that Ryan acted as a confidential source during the Government's covert criminal investigation into Endo's off-label marketing of Lidoderm. Dkt. 30 at 3. While that detail alone would make Ryan's contributions unusual and substantial, the Government's passing reference belies the personal and professional hardships that Ryan experienced while recording more than 200 hours of conversations over three years. Mulhall Declaration at 5; Ryan Declaration at ¶ 27. It undercounts the hundreds of hours that Ryan spent reviewing the thousands of pages of transcribed conversations, correcting incomplete or inaccurate transcriptions, and highlighting key conversations for the Government to review. Ryan Declaration at ¶ 27. Additionally, it understates the significance of what Ryan obtained in those recordings – the primary evidence of Endo's fraudulent conduct, obtainable only by an insider with access to high-level executives.

After the Government served the subpoena, Ryan was once again called upon to aid in the investigation by reviewing the responsive documents to help narrow the scope of the investigation and target the review to the most relevant information. Mulhall Declaration at ¶ 7; Ryan Declaration at ¶ 28. At the Government's request, Ryan and her counsel signed an "Agreement Regarding Common Interest and Disclosure of Information" on March 13, 2008, enabling the Government to disclose information that is protected by the attorney-client privilege, work product doctrine, investigative privilege, or other privileges. One week after entering into the Agreement, Ryan had a phone call with Capezza, Mulhall, Barnes and AUSA Nicole Mark of the Eastern District of Pennsylvania to discuss Endo's document production and

to get Ryan's guidance on search terms and parameters to narrow the review of the responsive documents. Ryan Declaration at ¶ 28.

Ryan continued to supplement the Government's investigation while she stayed in her position as a Specialty Sales Representative. Mulhall Declaration at ¶ 8; Ryan Declaration at ¶ 29. Ryan continued to attain honors within the company, assuring that she would be held in a position of esteem and allowed access to senior management. For example, in 2010, Ryan was one of two sales representatives awarded a second trip to Japan as the recipient of the "Ever Shining Sun Award," one of the highest honors in the company. Ryan Declaration at ¶ 6. Ryan received and produced to the Government new off-label studies, company-wide voicemails including one from an Endo executive regarding the termination of certain sales representatives for off-label marketing, and memoranda regarding the changing policies of maintaining and ultimately eliminating Restricted Materials Logs (which Ryan identified was the result of corporate concerns that the logs would be used as evidence against the company). Ryan Declaration at ¶ 29.

## B. Ryan's information was the primary contribution to the obtained result.

From the initial pre-filing disclosure provided to the FBI through the settlement of the case, the Government never indicated it had an alternate means to obtain the evidence that Ryan acquired through the recordings, the document production, and the access to high-level insider communications and presentations. The Government relied heavily on the suggestions made by Ryan, the allegations in her complaint, the initial document production, and conversations exposed in the covert recordings to develop the specific subpoena language. The Government's constant reliance on Ryan demonstrates that she was the primary source of insider information during the initial, active years of the investigation.

Moreover, from 2005 until the settlement in 2014, the Government did not expand the case beyond the off-label allegations that Ryan initially identified. No additional drugs were implicated, nor were any additional fraudulent schemes identified. Because the case stayed under seal for nearly nine years, the Government never engaged in formal discovery to expand or alter the direction of the investigation. There is nothing in the record or that has ever been disclosed to Ryan or her counsel to suggest that the Government's liability or damage calculations changed or increased by the appearance of the two late-filed relators, whose claims overlapped those previously brought by Ryan. Mulhall Declaration at ¶ 9. Therefore, every dollar of the \$197.2 million settlement – even those which the Government allocated to criminal conduct – was derived from Ryan's off-label allegations. Mulhall Declaration at ¶ 10, 11.

Further, Ryan and her counsel are also largely responsible for the settlement because they recognized that the investigation was languishing in 2010, and then independently assumed the responsibility for pushing the investigation forward, thereby preventing it from closing without a proper resolution. Ryan Declaration at ¶ 30; Scudieri Declaration at ¶ 8. Despite the initial surge of investigation into Ryan's allegations from 2005 through 2008, the investigation noticeably slowed down in 2010 amid issues of limited Government financial resources and significant turn-over in the agents and prosecutors responsible for the investigation. *Id.* With a goal of reinvigorating the enthusiasm with which the case was originally pursued, Ryan and her counsel undertook the task of acquainting each new agent and prosecutor with the off-label allegations, the information obtained by Ryan's recordings and the subpoena, and the potential damages. Ryan Declaration at ¶ 31. To accomplish this, the James Hoyer firm employed two unique resources: its in-house video production department and its proprietary case management

system called Genu which relies on a narrative-style platform to present and organize all of the salient information in a case.

In January 2012, Ryan traveled to Tampa for three days to be interviewed and filmed at length by Angie Moreschi, James Hoyer's Investigative Producer and ten-time regional Emmy Award winner for broadcast journalism. Ryan Declaration at ¶ 31. The effort resulted in an 18-minute documentary summarizing the case, the evidence, and the damages caused by Endo's ongoing conduct. Scudieri Declaration at ¶ 8. Based on James Hoyer's knowledge and communications with other *qui tam* counsel, a video production of that nature was unprecedented in False Claims Act cases. To reinvigorate the investigation, James Hoyer distributed the video to every agent and prosecutor known to be involved in the case. *Id.* The case was still sealed from the defendants at the time of the video production, but once Ryan's identity was disclosed to Endo during the settlement negotiations, James Hoyer gave permission to the Government to share the video with the defendants so they would have a better understanding of the magnitude of the case that had been built against them. The 18-minute documentary is attached to the Scudieri declaration as Exhibit B-1.

Additionally, to facilitate familiarity with the investigation, James Hoyer created log-in access to the firm's proprietary, internally-developed, case management system, Genu. Scudieri Declaration at ¶ 9. Genu is a secure, web-based platform that allows attorneys to manage the extraordinary amount of information associated with False Claims Act cases in a linkable, illustrated narrative format. The Genu system also includes document management where James Hoyer continuously catalogued all source material (documents, audio recordings, video recordings, etc.) related to the case, and a Hopper where salient information from each document can be culled and stored in an issue-based library for easy access and use. The Genu system can

be accessed and edited from any web-browser, so information is readily available to anyone with access to the system. James Hoyer created log-in access so the Government could be constantly apprised of any new information obtained by Ryan, and could have a cohesive presentation of the case to provide to anyone newly assigned to the case. *Id.* An excerpt of the James Hoyer narrative in Genu related to the Endo investigation is attached to the Scudieri declaration as Exhibit B-2.

# C. The Government did not know about the fraud prior to Ryan coming forward.

This factor is not in dispute. There is no suggestion in the record and no one has ever suggested to Ryan or James Hoyer that the Government was aware of Endo's rampant, intentional off-label marketing and promotional scheme prior to Ryan's allegations. Scudieri Declaration at ¶ 6. The Government, twice given the opportunity to submit briefs on the relator's share dispute, did not make any statements indicating it had prior knowledge of the fraud before Ryan came forward. Dkts. 30, 38. Indeed, former FBI agent Mulhall specifically states that he initiated the FBI's investigation, "[b]ased on the information provided by Ryan." Mulhall Declaration at ¶2. Additionally, it is reasonable to assume that AUSA Marilyn May would not have represented to Ryan's counsel that the Eastern District of Pennsylvania would advocate that, "Ms. Ryan receive a significant percentage recovery of the federal share of the civil settlement," if the Government was already on the trail of the fraud prior to Ryan's allegations. Scudieri Declaration at ¶10.

Of note, when Ryan first disclosed the off-label scheme, the allegations had a widespread impact across many Governmental divisions and units. From Ryan's initial disclosure to the FBI and filing with the Department of Justice and Eastern District of Pennsylvania, the case eventually grew to encompass at least eleven different agencies leading or assisting the investigation: the U.S. Attorney's Office for the Eastern District of Pennsylvania, the DOJ Civil Division's Commercial Litigation Branch, the U.S. Attorney's Office for the Northern District of New York, the DOJ Civil Division's Consumer Protection Branch, the Federal Bureau of Investigation, the Food and Drug Administration Office of Criminal Investigation, the Department of Health and Human Services - Office of Inspector General, Office of Investigations, the Defense Criminal Investigative Service of the Department of Defense, the U.S. Postal Service - Office of Inspector General, the Office of Personnel Management Office of Inspector General, the Department of Health and Human Services - Office of Counsel to the Inspector General and Office of General Counsel, Center for Medicare and Medicaid Services, the Food and Drug Administration's Office of Chief Counsel, and the National Association of Medicaid Fraud Control Units.

D. Additional factors that are often considered by courts all weigh in favor of Ryan receiving the maximum or near maximum percentage as a relator's share award.

As illustrated by the foregoing analysis, the factors contemplated by the Senate in establishing the relator's share award militate in favor of Ryan receiving the maximum or near maximum percentage of the federal civil share of the settlement in recognition of her extraordinary contributions and commitment to the case. As discussed above, some courts have considered additional factors in reaching relator's share determination – either as part of the DOJ's Relator Share Guideline factors or simply as part of calculating a fair and reasonable award. Every additional factor that the Court may consider weighs in favor of increasing Ryan's relator's share award.

The question of whether a relator's personal hardships should be considered is highly disputed – some courts are adamant that personal strain and professional hardships are relevant,

while others say they simply are not part of the calculation. See *Thornton*, 79 F.Supp.2d at 658-59 ("[T]he Court realizes that Relator has been put through considerable personal and professional hardship in pursuing this action"), *contra Merena I*, 52 F.Supp.2d at 433 ("Nothing in the statute remotely suggests that these are appropriate considerations in determining the amount or proportionate share to be awarded *qui tam* relators."). Those courts that do choose to consider personal and professional hardships recognize the value in increasing a relator's award as encouragement to other relators to be willing to take on the same hardships. *Pedicone*, 807 F.Supp. at 1353; *Burr*, 882 F.Supp.2d at 168 ("The award of the maximum statutory amount in this instance is intended to encourage other potential whistleblowers to take similar risks in order to expose fraud against the United States.").

In the instant case, Ryan was not terminated from her job as a result of bringing her False Claims Act case, but she suffered tremendous stress by remaining in her job, under cover, for nearly eight years – more than half of her professional career. Ryan Declaration at ¶ 34. Ryan, who came forward to report the off-label marketing out of a personal sense of integrity and honesty, was forced to lie to her friends, family, and colleagues as the case languished under seal; was forced to feign as much shock and confusion as her colleagues as they hotly debated the cause of the Government's subpoena and who would have "ratted out" the company; and was forced to continue using sales tactics which she knew were improper just so she could maintain her level of respect within Endo and have continued access to senior management. *Id*.

Further, Ryan not only took extraordinary actions to aid the Government in obtaining a recovery, but she undertook any request asked of her while suffering from a long-term, chronic form of Lyme disease. Ryan Declaration at ¶ 33. While Ryan was not formally diagnosed until 2012, she had actually been suffering for nearly a decade without knowing the cause of her

ailments. The incredible mental and emotional stress of the case had exacerbated the previously-dormant illness such that the symptoms became crippling. Ryan still suffers from the residual effects of Lyme disease and has not been able to return to work.

Additionally, some courts consider whether a case went to trial when determining the appropriate percentage for a relator's share award, while others have expressly found that such a consideration is inappropriate. U.S. ex rel. Coughlin v. Int'l Business Machines Corp., 992 F.Supp. 137, 142 (N.D.N.Y. Jan. 15, 1998) (reserving maximum recovery for a relator who assists throughout complex pretrial proceedings and a lengthy trial), contra U.S. ex rel. Shea v. Verizon Communications, 844 F.Supp.2d 78 (D.D.C. Feb. 23, 2012) ("[T]he case law is clear that Relators may deserve a substantial percentage of the recovery even though no trial is necessary. Indeed, as a practical matter, the stronger the case and the more compelling the evidence at the time of filing and/or after discovery is completed, the less likely that it is that a defendant will take the risk of treble damages and civil penalties being awarded at trial...."). Because it is illogical to base the relator's share percentage solely on whether a trial occurred, it is more important to consider whether a relator was credible and would have been a strong Government witness if a case had gone to trial. There is no doubt that the Government deemed Ryan to be credible and trustworthy, as she was a confidential source for nearly a decade. See Shea, 844 F.Supp.2d at 87 ("[G]iven the initial materials [the relator] gave the Government and the on-going help he gave the Government lawyers and its auditors throughout the Government's investigation, one can only infer that the Government had concluded that he was indeed credible."). Ryan was willing and prepared to go to trial if the case had not been settled, and there is nothing to suggest that the Government had any reservations about her ability to competently and credibly testify at trial. Ryan Declaration at ¶ 34.

Finally, to the extent the Court is inclined to consider the DOJ's Relator Share

Guidelines, eleven of the fourteen factors for increasing the relator's share award plainly apply in
the instant case: (1) the relator reported the fraud promptly; (2) when she learned of the fraud, the
relator reported it to the Government; (3) the *qui tam* filing, or the ensuing investigation, caused
the offender to halt the fraudulent practices; (4) the complaint warned the Government of a
significant safety issue; (5) the complaint exposed a nationwide practice; (6) the relator provided
extensive, first-hand details of the fraud to the Government; (7) the Government had no
knowledge of the fraud; (8) the relator provided substantial assistance during the investigation
and/or pretrial phases of the case; (10) the relator's counsel provided substantial assistance to the
Government; (11) the relator and his counsel supported and cooperated with the Government
during the entire proceeding; (14) the filing of the complaint had a substantial adverse impact on
the relator. Factor (9) may arguably apply because, even though the case did not go to trial, the
Government clearly considered Ryan to be a credible witness. None of the Guideline's factors
for reducing the relator's share award applies to Ryan's contributions to the case.

### E. A small reduction may be appropriate.

Ryan maintains that she has been an exemplary relator who embodies all of the attributes that Congress envisioned when it established the relator's share award. Scudieri Declaration at ¶ 12. Indeed, Ryan did every single thing that was asked of her by the Government, and every single thing that she could think to do to bring this case to a resolution, and the percentage of her relator's share award should recognize those efforts. Ryan Declaration at ¶ 35. However, she is cognizant that it may be prudent for the Court to reserve the maximum 25% share for cases where the Government called upon a relator to participate in the extraordinary manner that Ryan did, and yet the case still required additional efforts to reach a resolution.

It is impossible to compare one case to another or to assign a percentage value to each aspect of an investigation: Does a relator whose case was quickly unsealed and resolved at trial after a year or two of discovery merit more or less than a relator put through a decade of covert investigation but whose case was resolved by settlement? Ryan asserts that the appropriate evaluation is whether, under the circumstances called for by each individual case, the relator contributed the maximum amount of effort possible to reach a successful resolution. Ryan did all that she could possibly have done to aid in the investigation of Endo and her extensive efforts led to the case being successfully resolved without the prolonged effort of extensive discovery or the uncertainty and effort of trial.

#### V. Conclusion

For the foregoing reasons, Relator Peggy Ryan respectfully requests that this Court order the United States of America to pay Ryan 24% of the federal civil recovery as a relator's share award in recognition of Ryan's extraordinary contributions to the Endo Pharmaceuticals settlement.

Respectfully submitted this 18th day of November, 2014,

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# **Certificate of Service**

I, John Newcomer, hereby certify that Relator Peggy Ryan's Motion for Relator's Share Award was served upon all parties of record this 18th day of November, 2014 via the CM/ECF service.

/s/ John R. Newcomer
John R. Newcomer, Jr. (PHV)